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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/690,173 10/16/00 SHANNON

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IP ADMINISTRATION
LEGAL DEPARTMENT 20BN
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EXAMINER

EPPS, J

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 09/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/690,173

Applicant(s)

SHANNON, KAREN W.

Examiner

Janet L. Epps

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. **WILLIAM N. PHILLIPS**
PATENT ANALYST

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 32-40 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 32-37, and 39-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al.

The instant claims are interpreted as reading on a composition comprising an oligonucleotide promoter-primer comprising an RNA polymerase promoter sequence. Since the presence of the instructions in the kit does not material effect the contents of the kit, the instructions are considered an intended use of the composition and therefore are not deemed to hold any patentable weight for prior art purposes. The prior art is applied on the basis of the prior art disclosure of the claimed composition.

Wang et al. provides kits for use in a method for mRNA amplification, where such kits may comprise containers, each with one or more of the various reagents (typically in concentrated form) utilized in the methods, including, for example, buffers, the appropriate nucleotide triphosphates (e.g., dATP, dCTP, dGTP and dTTP; or rATP,

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rCTP, rGTP and UTP), reverse transcriptase, DNA polymerase, RNA polymerase, and one or more primer complexes of the present invention (e.g., poly(T) or random primers linked to a promoter reactive with the RNA polymerase). A set of instructions will also typically be included, where the instructions may be associated with a package insert and/or the packaging of the kit or the components thereof (col. 11, lines 3-15). In a preferred embodiment of the Wang et al. invention, suitable DNA polymerases will be selected from M-MLV reverse transcriptase lacking RNaseH activity, and DNA polymerases selected from HTLV-1, HIV, BLV, Taq and Tth (col. 5, lines 29-50).

Wang et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 32-36 and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Phillips et al.

Phillips et al. discloses compositions for linear amplification of mRNA from a single living cell. The composition used for cDNA synthesis from the mRNA isolated from the living cell comprises a primer comprising a T7 polymerase promoter sequence and an oligo(dT)₂₄ sequence; dideoxynucleotide triphosphates, and avian myeloblastosis virus reverse transcriptase. The composition for use antisense RNA synthesis from the cDNA synthesized in the first step comprises T7 RNA polymerase and ribonucleotide

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triphosphates ATP, GTP, UTP and CTP. The compositions used in the method for linear amplification of mRNA described by Phillips et al. read on the contents of the kit recited in the instant claims particularly wherein said kit comprises: an oligonucleotide comprising an RNA polymerase promoter sequence, at least one polymerase, further comprising an RNA polymerase, wherein said RNA polymerase is T7 RNA polymerase.

Phillips et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 recites "[T]he kit according to Claim 32, wherein the kit comprises a first RNaseH- polymerase and a second RNaseH+ polymerase." The term "second RNaseH+ polymerase" as used in this context is vague and indefinite since there is no mention of a "first RNaseH+ polymerase" recited in the instant claim or in claim 32. There is insufficient antecedent basis for this limitation in the claim.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Janet L Epps
Examiner
Art Unit 1635

JLE
September 25, 2001